DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 4, 2014

Kostec Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 E. Chapman Avenue, Suite 110
FULLERTON CA 92831

Re: K141891
Trade/Device Name: Medical LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: July 7, 2014
Received: July 14, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141891

Device Name
Medical LCD Monitor

Indications for Use *(Describe)*

The Medical LCD Monitor is intended to be used in displaying and viewing medical digital images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 08/01/2014

1. Applicant / Submitter

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2. Submission Correspondent

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3. Device

- Trade Name: Medical LCD Monitor (Model: KT-D213V5E)
- Classification Name: Picture archiving and communications system
- Classification regulation: 21 CFR 892.2050
- Product Code: PGY

4. Predicate Device:

Wide 5MP (Mammo) LCD Monitor System (K052312) by WIDE Corporation

5. Description:

The Medical LCD Monitor (Model: KT-D213V5E) is designed for the purpose of medical applications such as X-ray, radiology, MRI, endoscopy or mammography imaging display. The high-resolution LCD panel with a resolution of 2560 x 2048, combined with a high performance image processing controller, provides the users high-definition and high-quality medical image displays. The medical monitor complies with international EMC/ safety standards.

6. Indications for use:

The Medical LCD Monitor is intended to be used in displaying and viewing medical digital images

for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications.

7. Comparison to the Cleared Device

The Medical LCD Monitor (KT-D213V5E) is substantially equivalent to the predicate device with respect to technical characteristics, performance, application and intended use. The specifications of the primary component employed by the subject device are the same as those of the predicate device and other differences have been independently validated. Any differences such as clock speed between the devices do not affect safety or effectiveness.

	Predicate Device	Subject Device
Device Name	5MP (Mammo) LCD Monitor System	Medical LCD Monitor
510K Number	K052312	-
Manufacturer	WIDE Corporation	Kostec Co., Ltd.
Indications for Use	The 5MP (Mammo) LCD Monitor System is intended to be used in displaying and viewing medical digital images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications.	The Medical LCD Monitor is intended to be used in displaying and viewing medical digital images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications.
Panel	TFT AMLCD IPS	TFT AMLCD IPS
Screen size	21.3" (422.4(H) x 337.92(V) [mm])	21.3" (422.4(H) x 337.92(V) [mm])
Pixel pitch	0.165(H) x 0.165(V) [mm]	0.165(H) x 0.165(V) [mm]
Contrast ratio	850:1	850:1
Declared and actual array size	422.4(H)x337.92(v)mm	422.4(H)x337.92(v)mm
Max and min achievable luminance	Typ: 1,100 cd/m2	Typ: 1,100 cd/m2
Luminance Calibration	Software(Optional) Sensor (optional)	Software(Optional) Sensor (optional)
Intrinsic bit-depth of the panel	8bit	8bit
True output bit-depth by performing visual test	14bit	14bit
Luminance Uniformity	min : 70 L.U =(Min.lum /Max.lum.)*100	min : 70 L.U =(Min.lum /Max.lum.)*100
Chromaticity measured at 5, 50 and 95% (fefxox ISO13406-2)	x:0.294, y:0.309	x:0.294, y:0.309
Clock speed	64.5MHz	74 MHz
Spatial resolution, spatial MTF	2,560(H)x2,048(V)	2,560(H)x2,048(V)

8. Performance Data

The following tests have been performed on the subject device and passed the pre-set criteria.

- Luminance Response
- Uniformity
- Miscellaneous Test
- Display Reflection
- Angular dependencies
- Clinical Reference Image
- Geometric Distortion
- Display Noise
- Display Veiling Glare
- Scheduler Table
- EMC and Electrical Safety Tests
- Software Verification and Validation

9. Conclusion

We have concluded that our devices are substantially equivalent to the predicate device in safety and effectiveness. No new questions of safety and effectiveness have been raised.